**(Site Reported)**

**Run Date : 02/25/2009 8:45:10 AM**

# Adverse Event Expedited Report

**Protocol Number :**6246 **CTC Version :**CTCAE v3.0 **Principal Investigator :**

**Title :**Phase II Evaluation of FTI (R115777) in Treatment of Relapsed and Refractory Lymphoma

**Institution :**Mayo Clinic Rochester **Report Type :** **Ticket #:** **Amendment #:**

**Created Date :**02/25/2009

## Reporter Information

**Reporter Name :** Robbin Peterson
**Phone :** 507-776-3234 **Fax :** 999-999-9999 **Email :** peterson.robbin@mayo.edu

**Submitter Name :** Robbin Peterson
**Phone :** 507-776-3234 **Fax :** 999-999-9999 **Email :** peterson.robbin@mayo.edu

**Physician Name :** Robbin Peterson
**Phone :** 507-776-3234 **Fax :** **Email :** peterson.robbin@mayo.edu

## Patient Information

| | | | | | |
|---|---|---|---|---|---|
| **Patient ID :** | ex5632 | **Birth Date :** | 08/ 20/ 1975 | **Gender :** | Female |
| **Race :** | White | **Ethnicity :** | Not Hispanic or Latino | | |
| **Height(Centimeter ) :** | 153 | **Weight(Kilogram ) :** | 57 | **Body Surface Area :** | 1. 556 |

**Baseline performance status at initiation of protocol - ECOG/Zubrod scale :** 0 = Normal Activity, asymptomatic
**Disease Name :** Hodgkin lymphoma, NOS
**Disease Name Not Listed :**
**Primary Site of Disease :** Lymphnode
**Date of Initial Diagnosis :** 03/2004

## Course Information

**Treatment Assignment Code :** TAC1
**Description :** R115777: 300 mg PO bid on Days 1-21, every 28 days x 2. Note: If responding or stable disease after 2 cycles, pts. may continue with therapy.
**Start date of first course :** 11/21/2008
**Start date of course associated with Expedited Report :** 02/14/2009
**Start date of primary AE :** 02/16/2009
**End date of primary AE :**
**Course Number on which event(s) occurred :** 4
**Total number of courses to date :** 4
**Was Investigational Agent(s) administered on this protocol?:** Yes

## Description of Event

**Description and Treatment of Event :** Patient admitted to the hospital on 2/16/09 with a history of Hodgkin's Lymphoma and worsening dyspnea. S/P mediastinal radiation and multiple rounds of chemotherapy, now on experimental therapy with tipifamib(LS038B). She also has a history of presumed pulmonary radiation damage(fibrosis, bronchiectasis). She has recently had a number of illnesses characterized by URI

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symptoms,dyspnea, and cough, with no specific etiology ever identified. Sha has generally had some improvements in her symptoms when treated with antibiotics and/or steroids. MOst recently she ahs been on cyclic antibiotics for her bronchiectasis(Augmentin,Levaquin,Azithromycin each for 1 week each 3 months) and has been on a steroid taper empirically for her pulmonary disease since January 09. A culture from bronchocscopy was unrevealing at this point. Cytology was negative for malignacy. Pathology shopwed acute lung injury,GMS stain for microorganism negative. Patient study drug was held on 02/19/2009, patient remains in the hospital under close observation.

| | | | |
|---|---|---|---|
| **Present Status :** | Not recovered/Not resolved | **Date of Recovery or Death :** | |
| **Retreated :** | No | | |
| **Removed from Protocol Treatment (to date) :** | No | **Date Removed from Protocol Treatment :** | |
| **Cause of Death :** | | | |
| **Death Date :** | | **Autopsy Performed :** | No |

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## Prior Therapies

| Therapy | Therapy Start Date | Therapy End Date | Comments | Chemotherapy Agents |
|---|---|---|---|---|
| Chemotherapy multiple agents systemic | 03//2004 | 09//2004 | ABVD | |
| Chemotherapy multiple agents systemic | 10//2004 | 11//2004 | DHAP | |
| Bone Marrow Transplant | 12//2004 | 01//2005 | Auto transplant | |
| Radiation Therapy | 03//2005 | 04//2005 | | |
| Chemotherapy single agent systemic | 03//2007 | 10//2008 | RAD-001 | |

## Pre-Existing Conditions

Bronchficctasis and Fibrosis, presumably secondary to mediastinal radiation

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## Protocol Agents

**Treatment Assignment Code :**

| Agent | Total Dose Administered this Course | Last Administered Date | Comments | Agent Adjustment | Agent Delayed | Delay |
|---|---|---|---|---|---|---|
| R115777 (tipifarnib, Zarnestra) | 3600mg | 02/19/2009 | | | | |

## Other Contributing Causes

Bronchietasis/Fibrosis

## Adverse Events (CTCAE)

| CTCAE CATEGORY | Adverse Event | Grade | Hospitalization or Prolongation of Hospitalization | Start Date | End Date | Is Primary AE? | Comments |
|---|---|---|---|---|---|---|---|
| PULMONARY/UPPER RESPIRATORY | Dyspnea (shortness of breath) | 3: Severe | 1: Yes | 02/16/2009 | | Yes | |

## Attribution for Adverse Events

| Attribute to | 3: Severe Dyspnea (shortness of breath) |
|---|---|
| Course | |
| R115777 (tipifarnib, Zarnestra) | 3: Possible |
| Other causes | |
| Bronchietasis/Fibrosis | 3: Possible |
| Disease | |
| Hodgkin lymphoma, NOS | 3: Possible |